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Phan et al.

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(54) **APPARATUS AND METHOD FOR
DEPLOYING STENT ACROSS ADJACENT
TISSUE LAYERS**

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(58) **Field of Classification Search**

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2/95; A61F 2/966; A61M 27/002

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See application file for complete search history.

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Primary Examiner — Brooke Labranche

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Wickhem, LLP

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A61F 2/95 (2013.01)

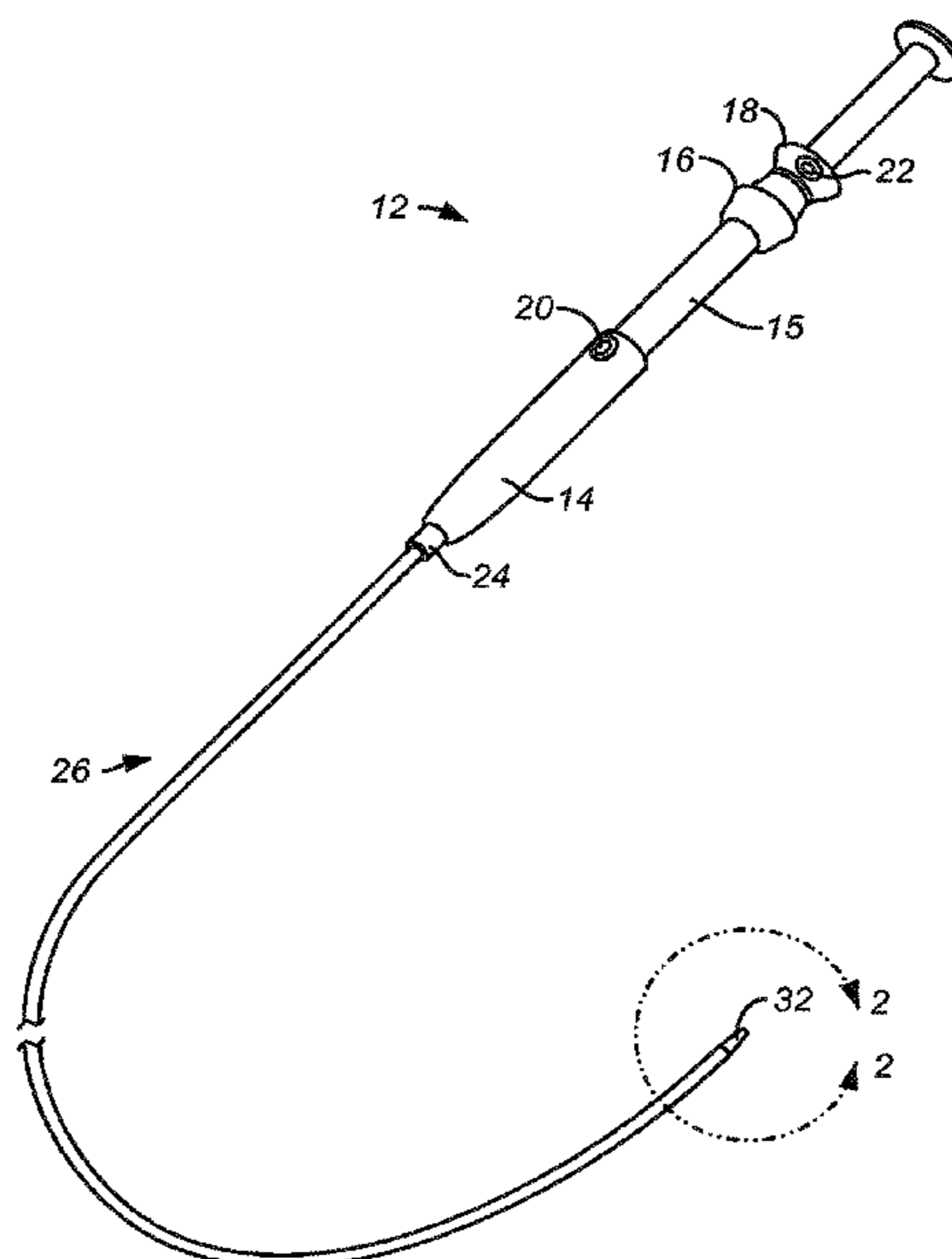
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(57) **ABSTRACT**

Transluminal access system includes a stent delivery cath-
eter having a handle control mechanism. The catheter com-
prises a number of components for establishing an initial
penetration between adjacent body lumens and subsequently
implanting a stent or other luminal anchor therebetween.
Manipulation of the stent components is achieved using
control mechanisms on the handle while the handle is
attached to an endoscope which provides access to a first
body lumen.

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(2013.01); *A61B 17/11* (2013.01); *A61F 2/95*
(2013.01); *A61F 2/966* (2013.01); *A61B*

16 Claims, 8 Drawing Sheets



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continuation of application No. 13/364,265, filed on Feb. 1, 2012, now Pat. No. 9,888,926, which is a continuation of application No. 12/772,762, filed on May 3, 2010, now Pat. No. 8,357,193.

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A61B 17/34 (2006.01)
A61M 27/00 (2006.01)

(52) **U.S. Cl.**

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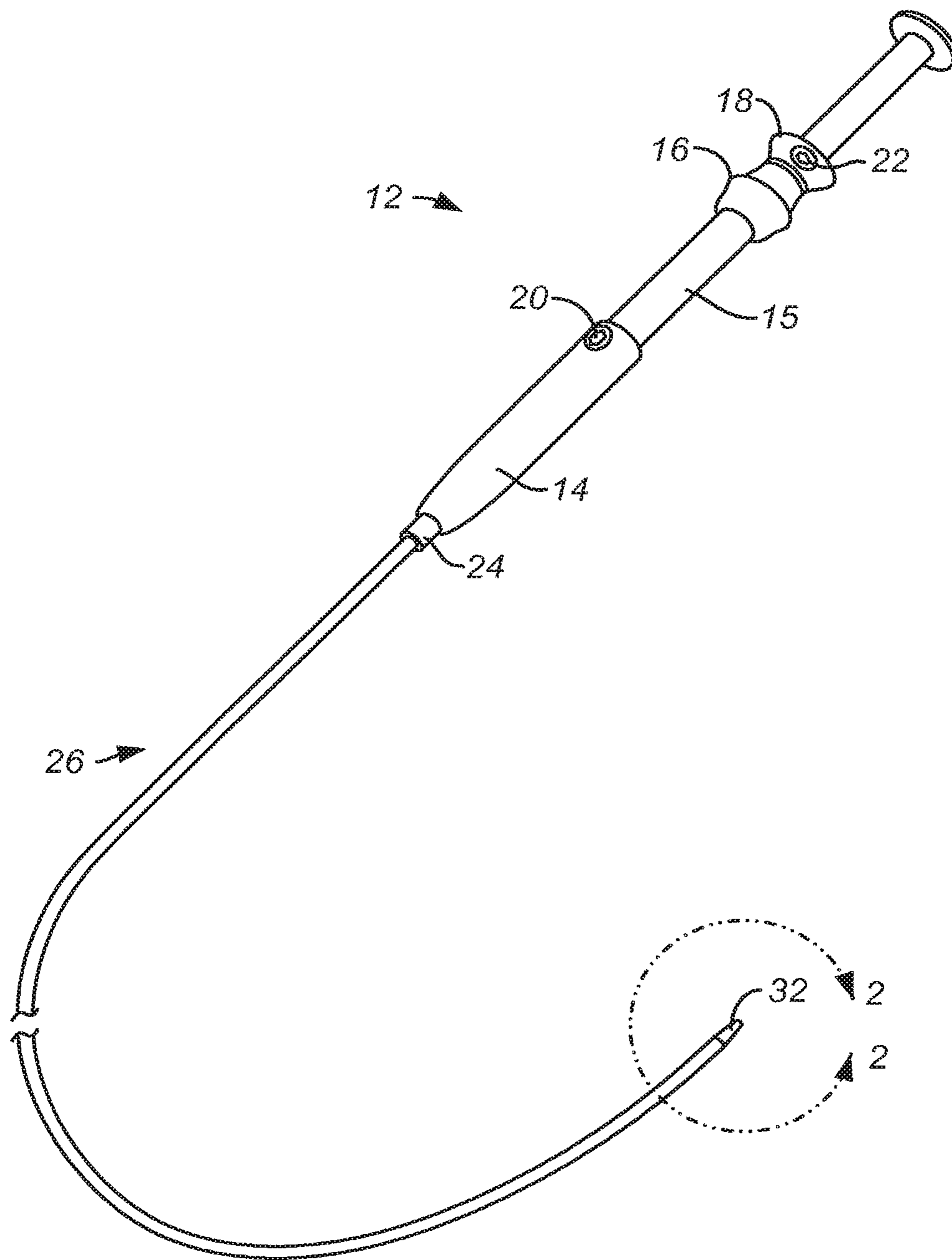


FIG. 1

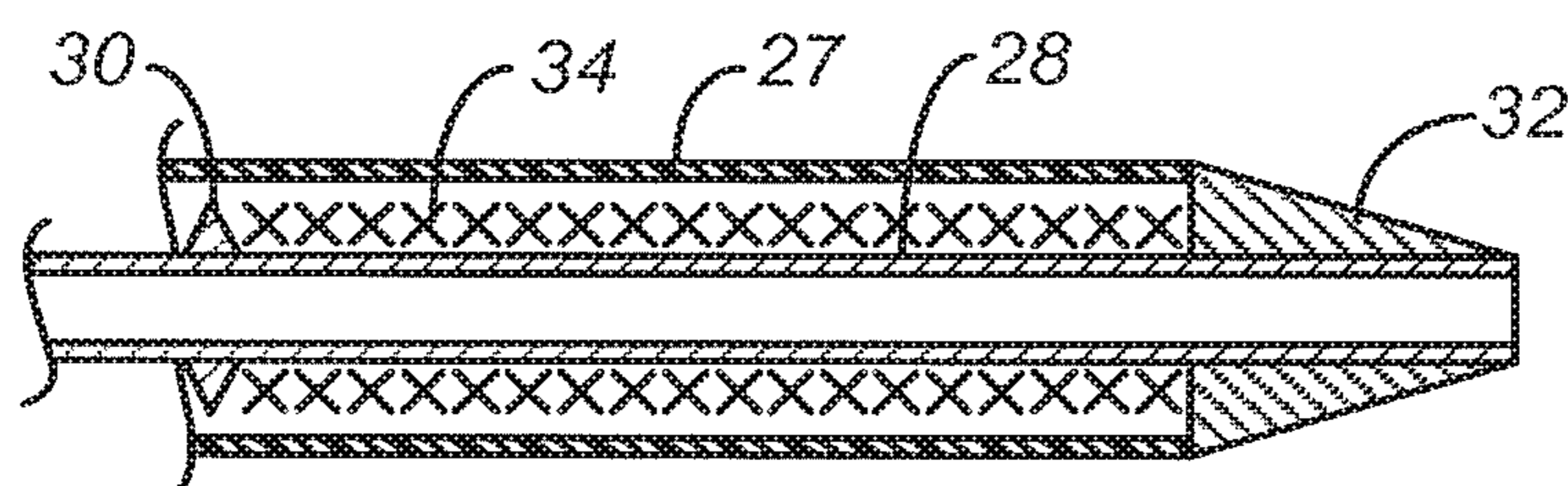
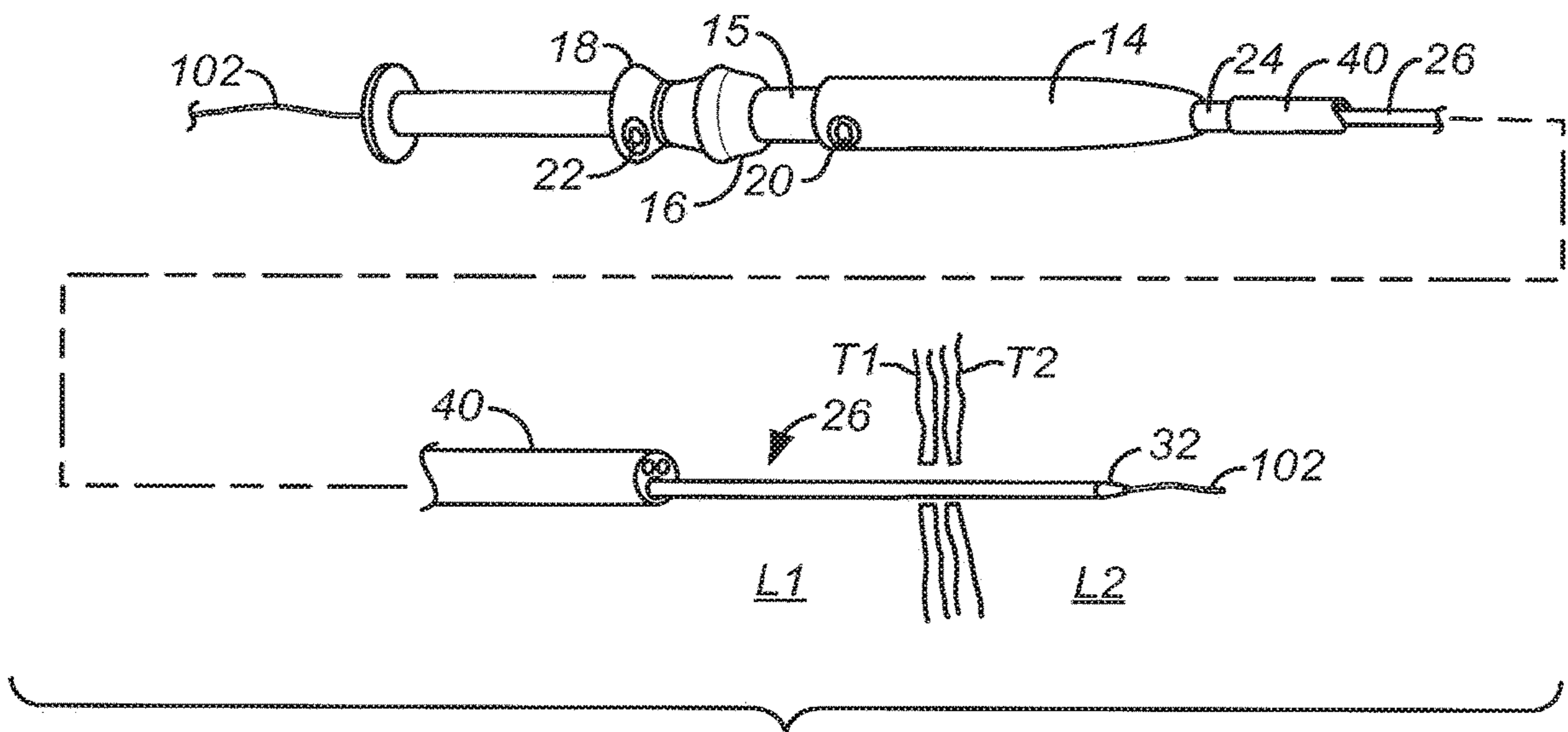
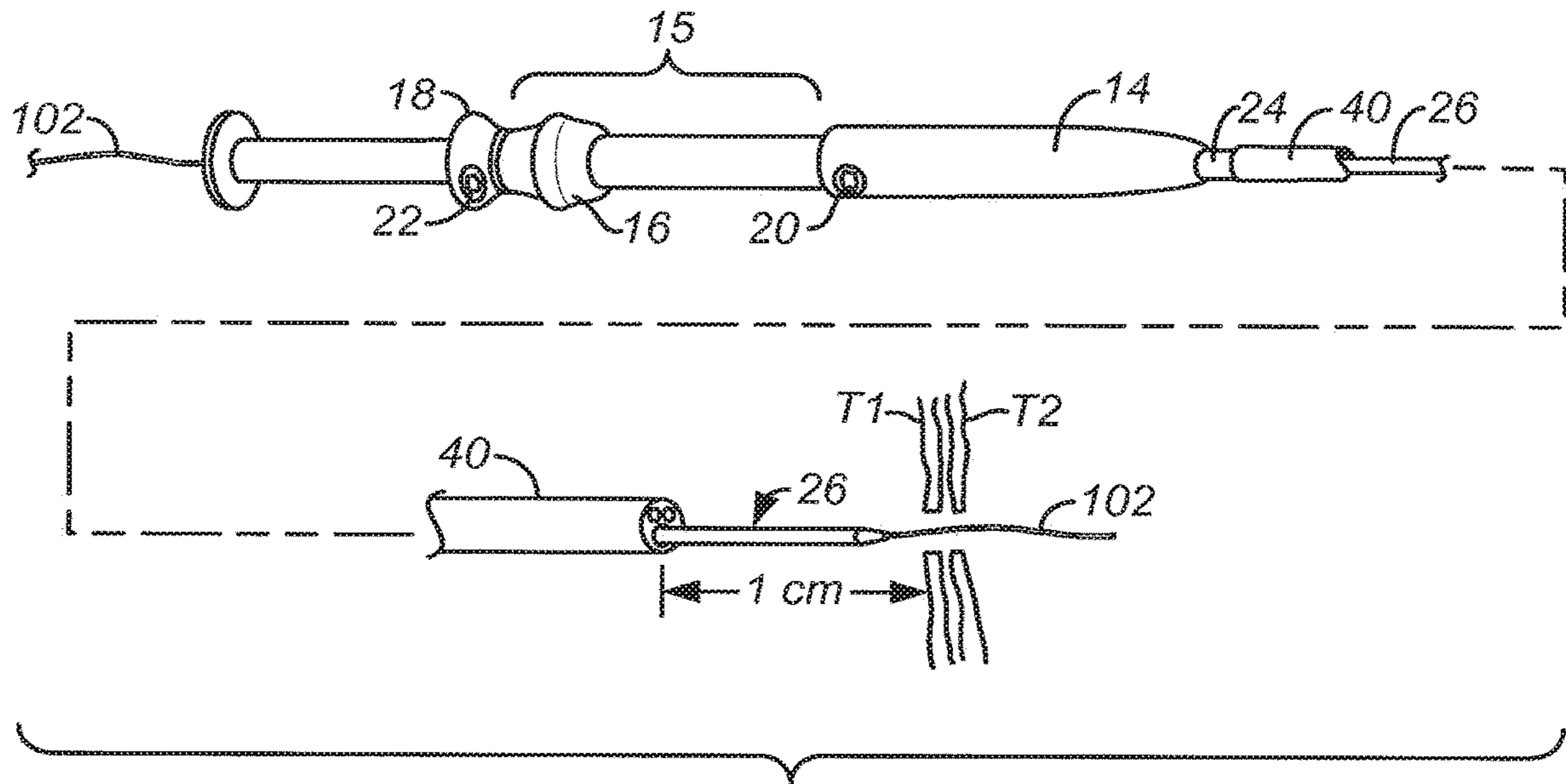


FIG. 2



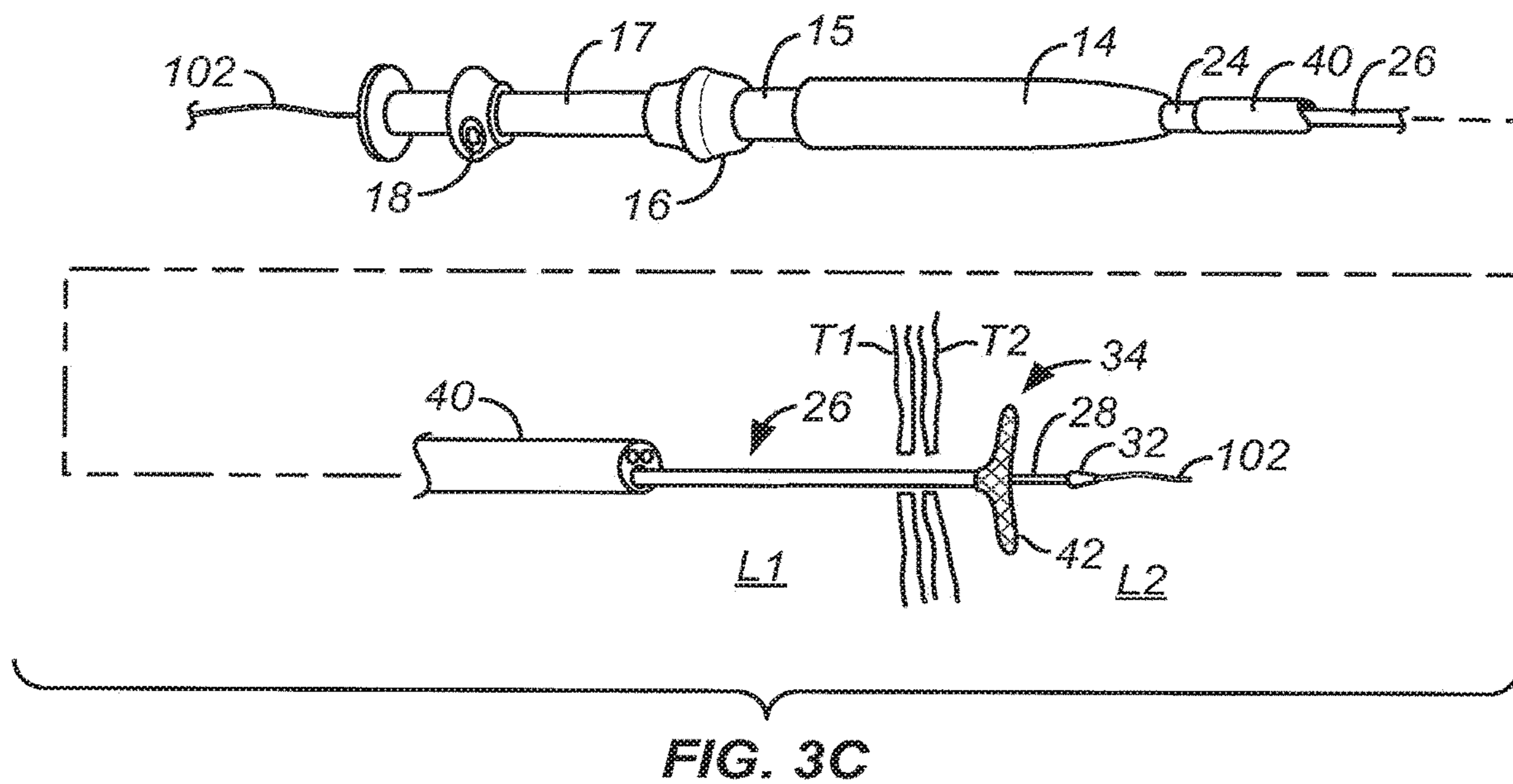


FIG. 3C

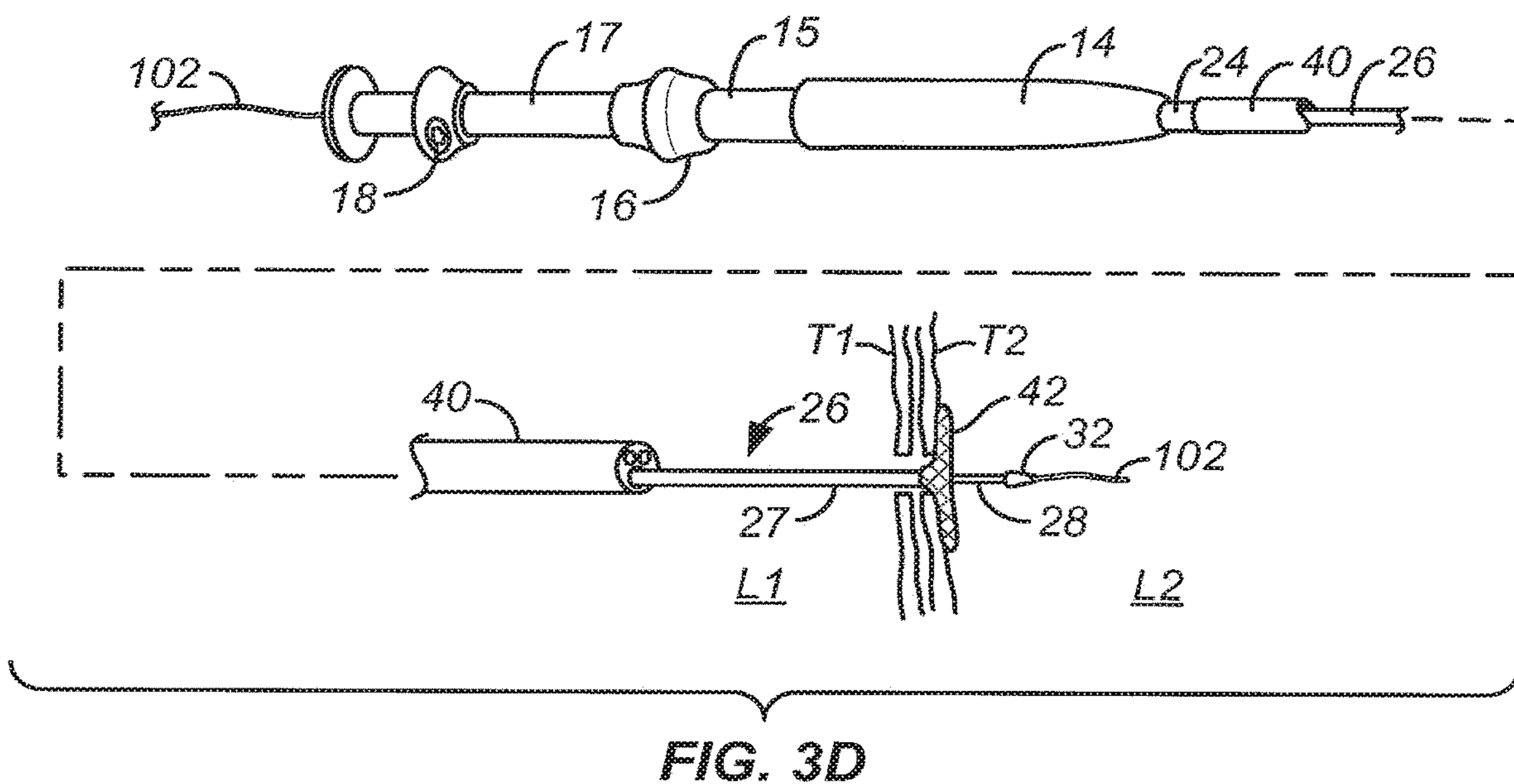


FIG. 3D

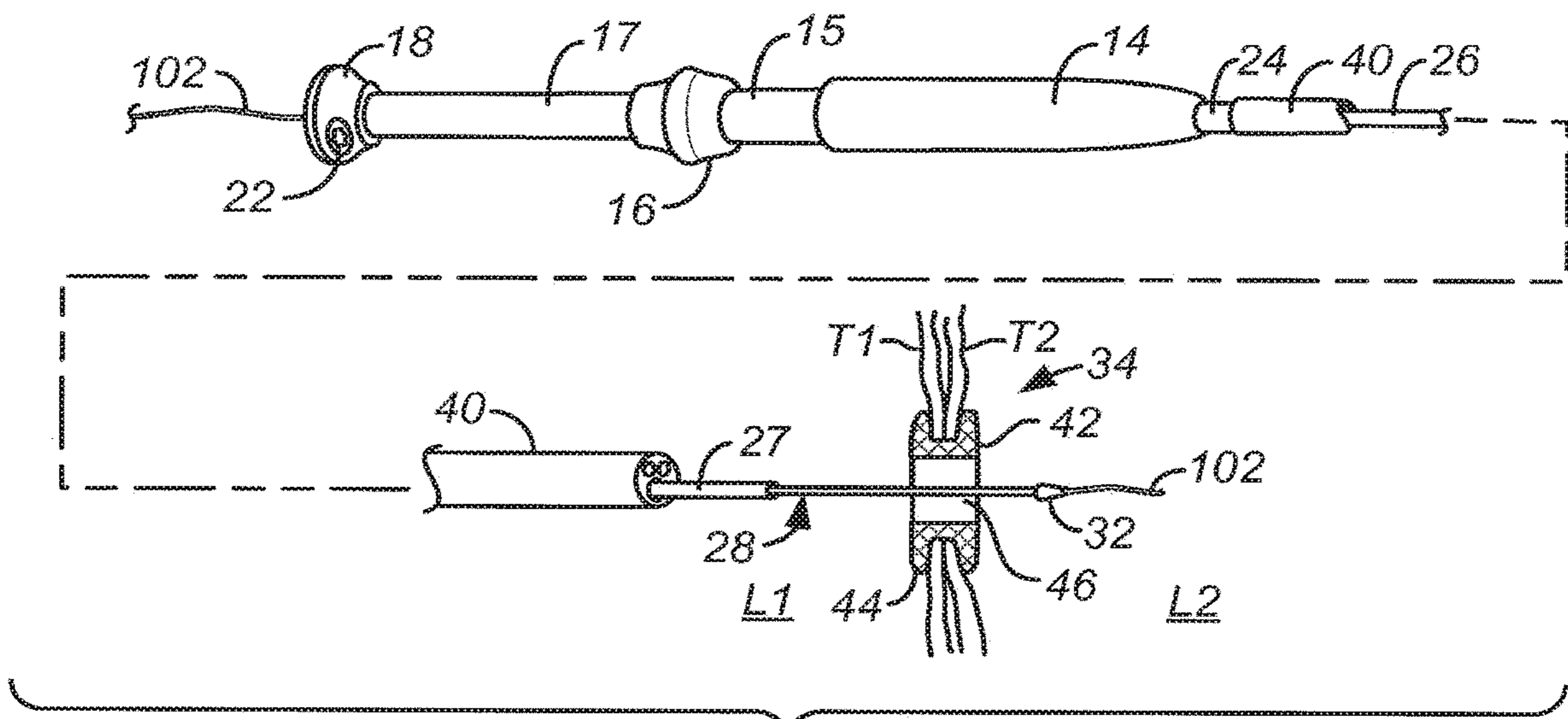


FIG. 3E

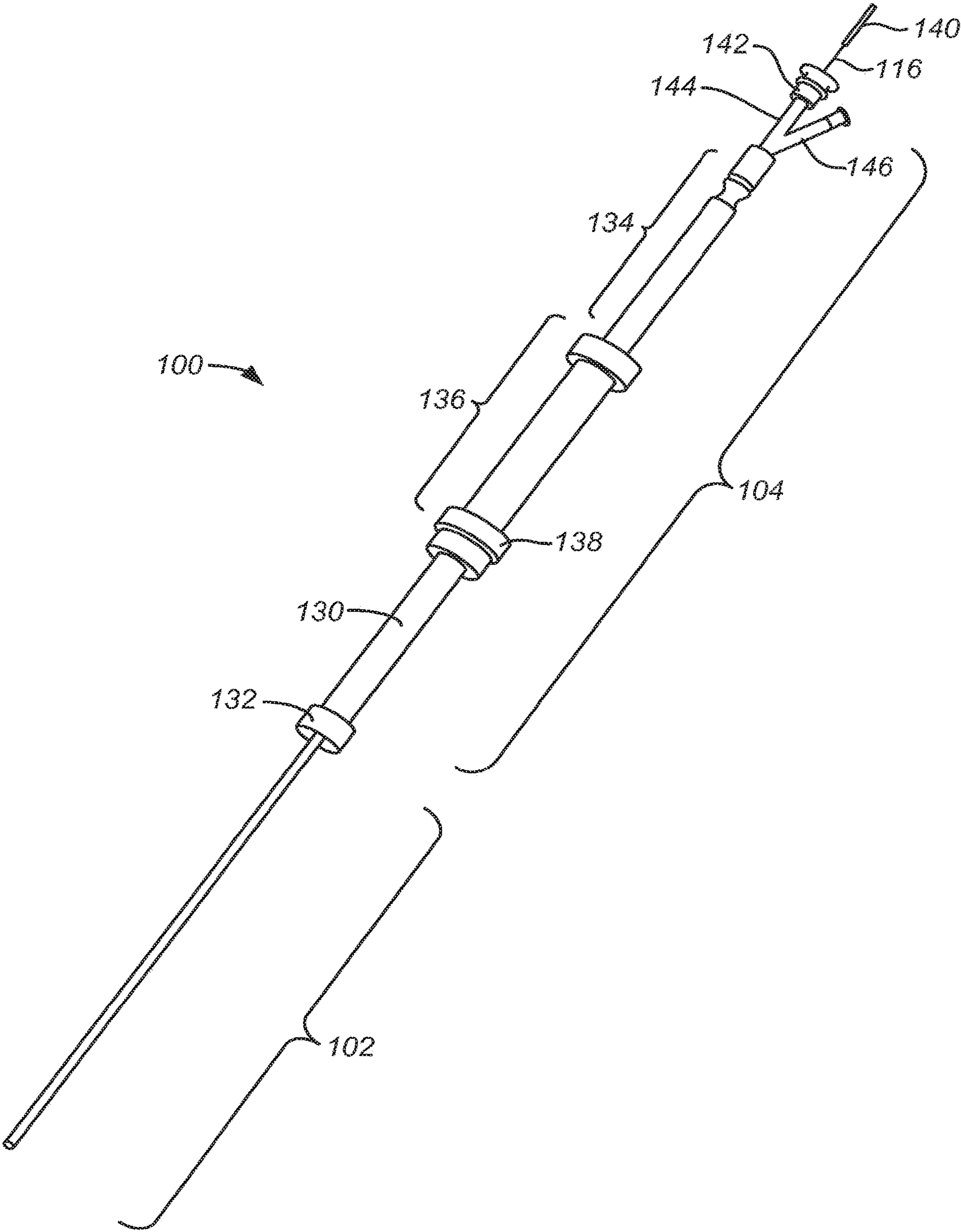


FIG. 4

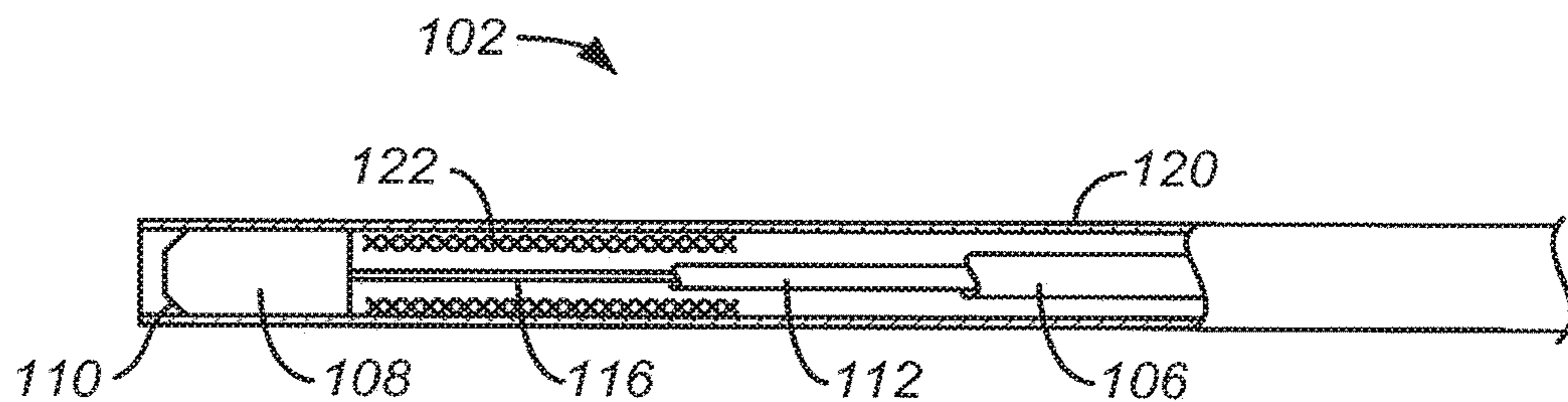


FIG. 5A

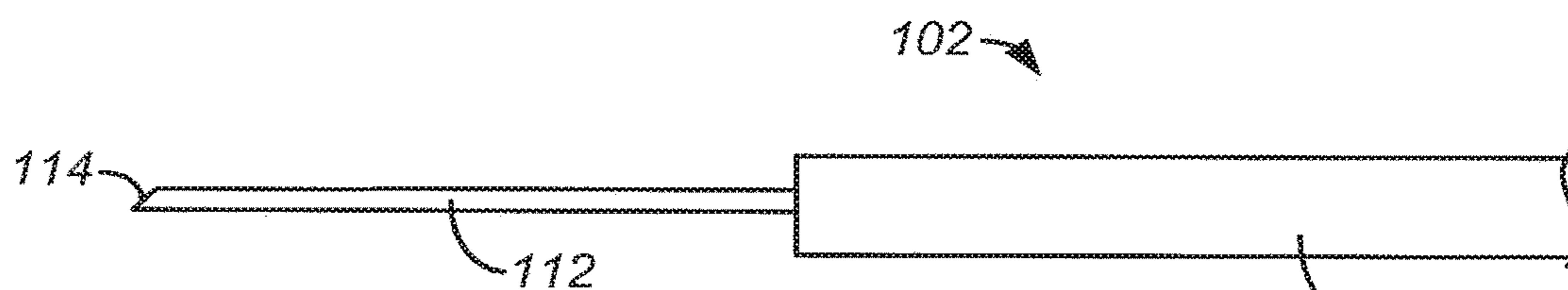


FIG. 5B

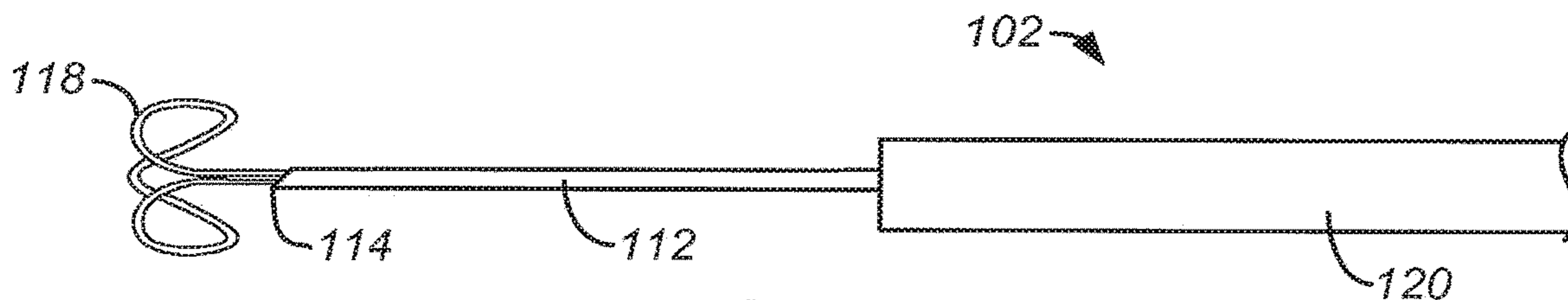


FIG. 5C

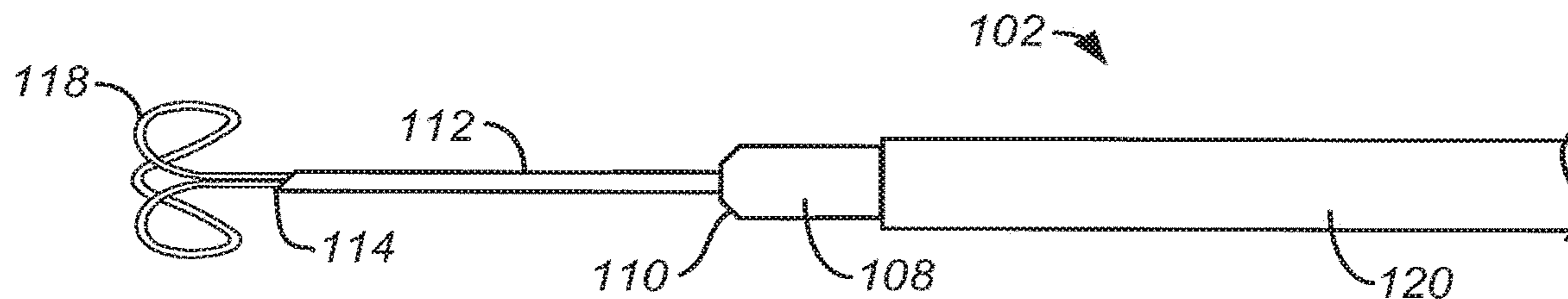


FIG. 5D

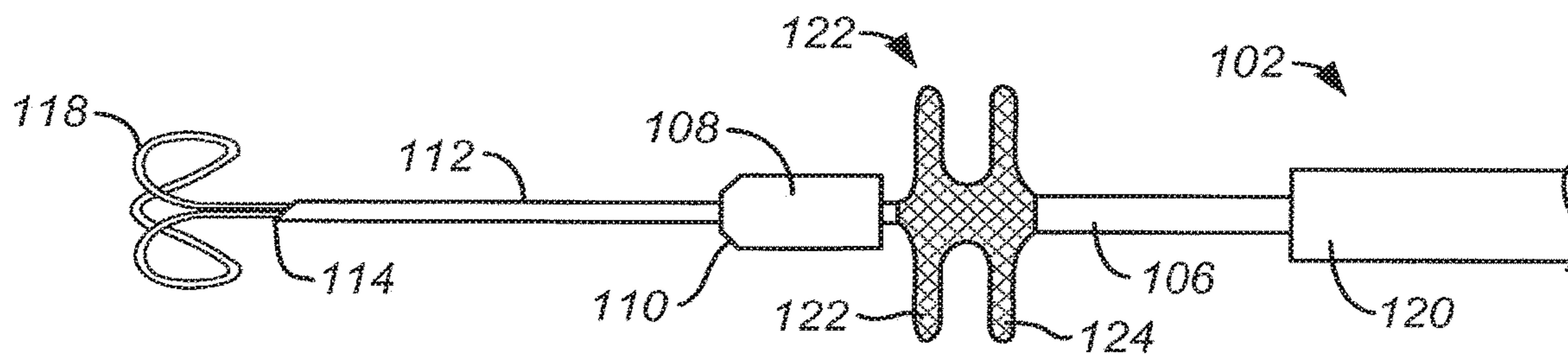


FIG. 5E

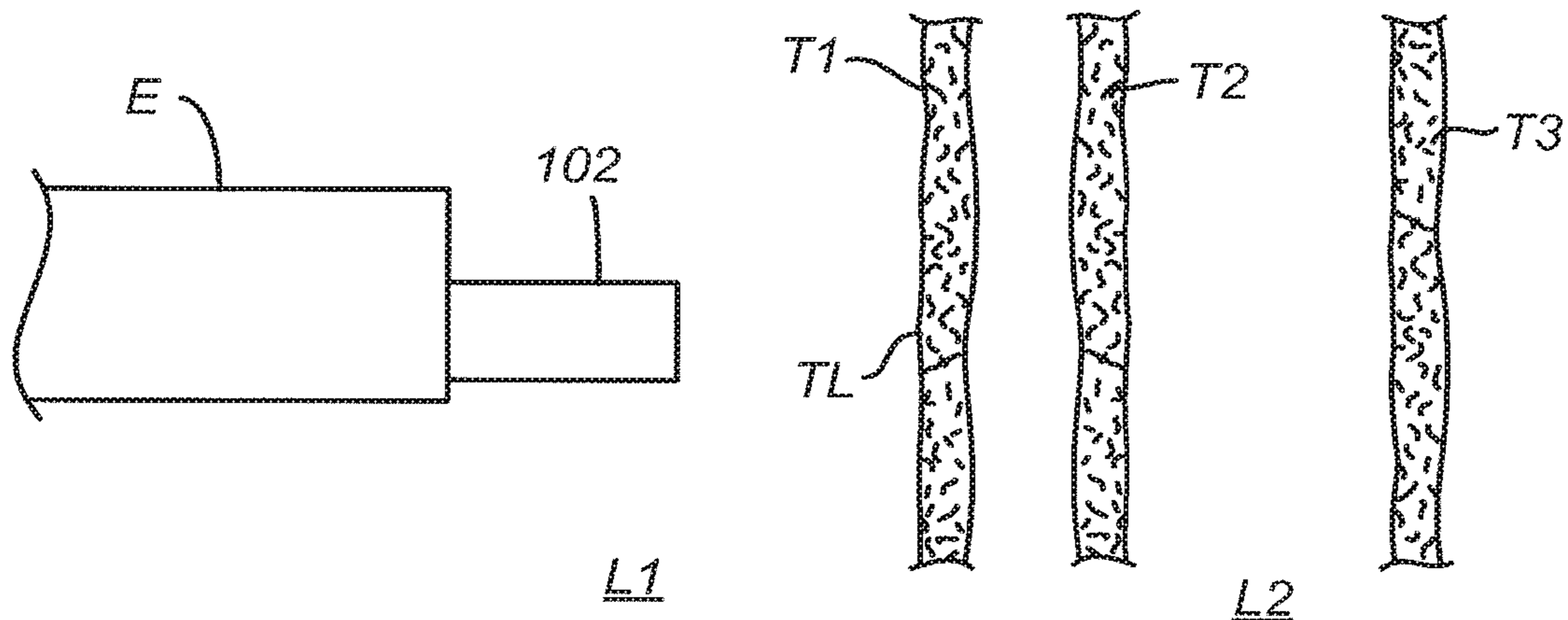


FIG. 6A

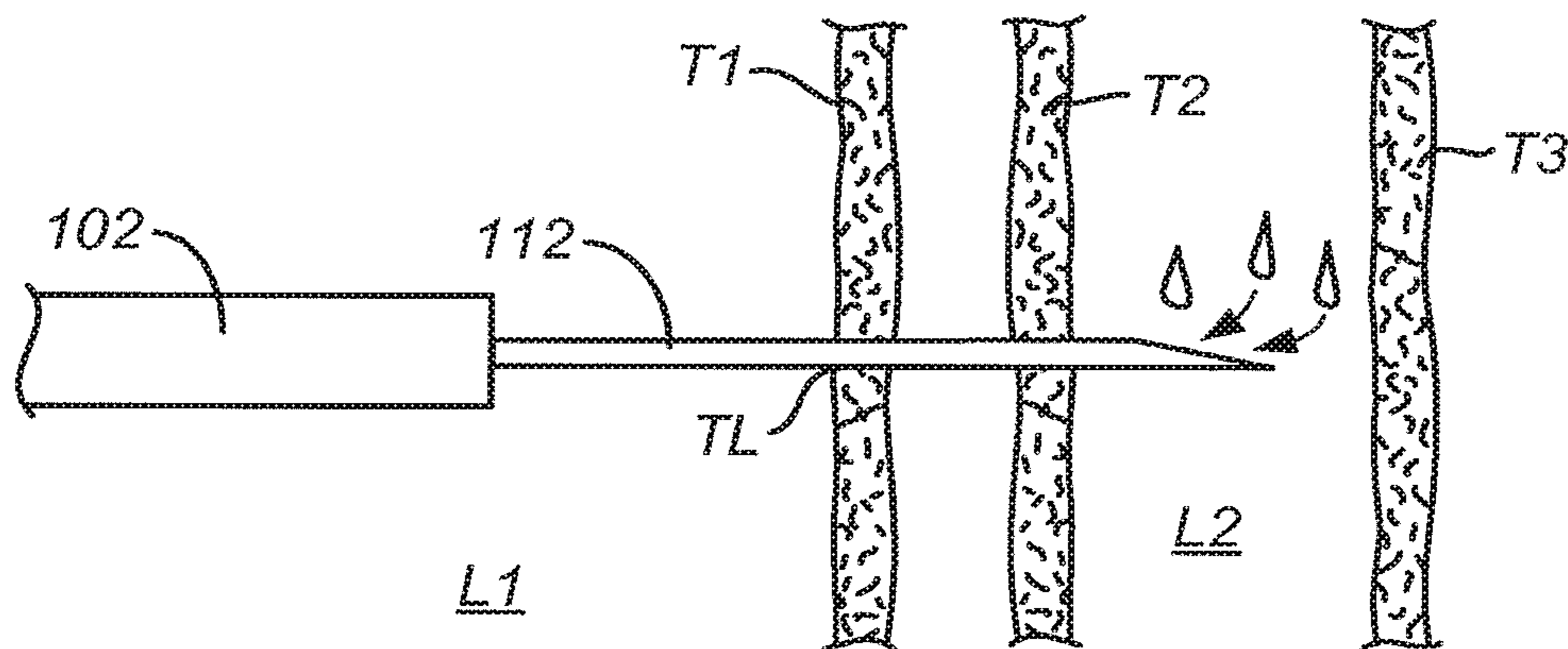


FIG. 6B

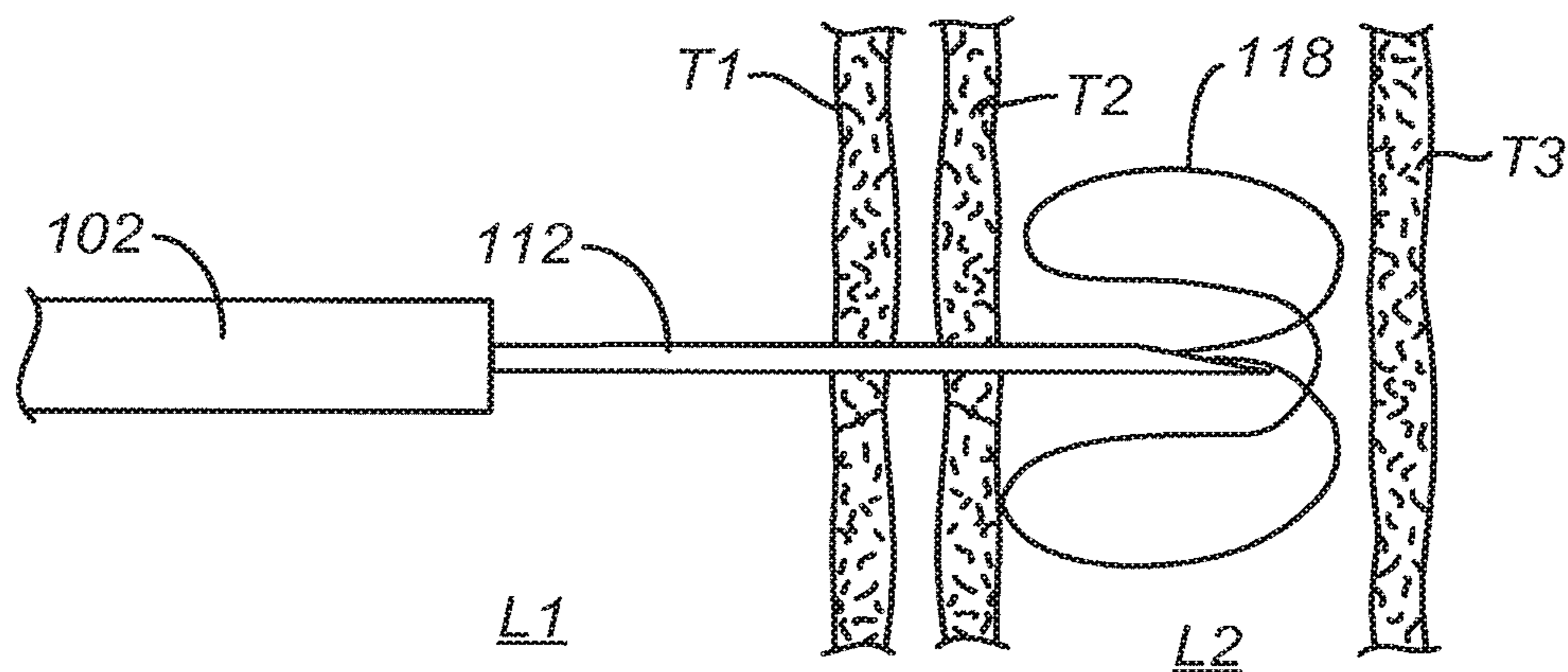


FIG. 6C

FIG. 6D

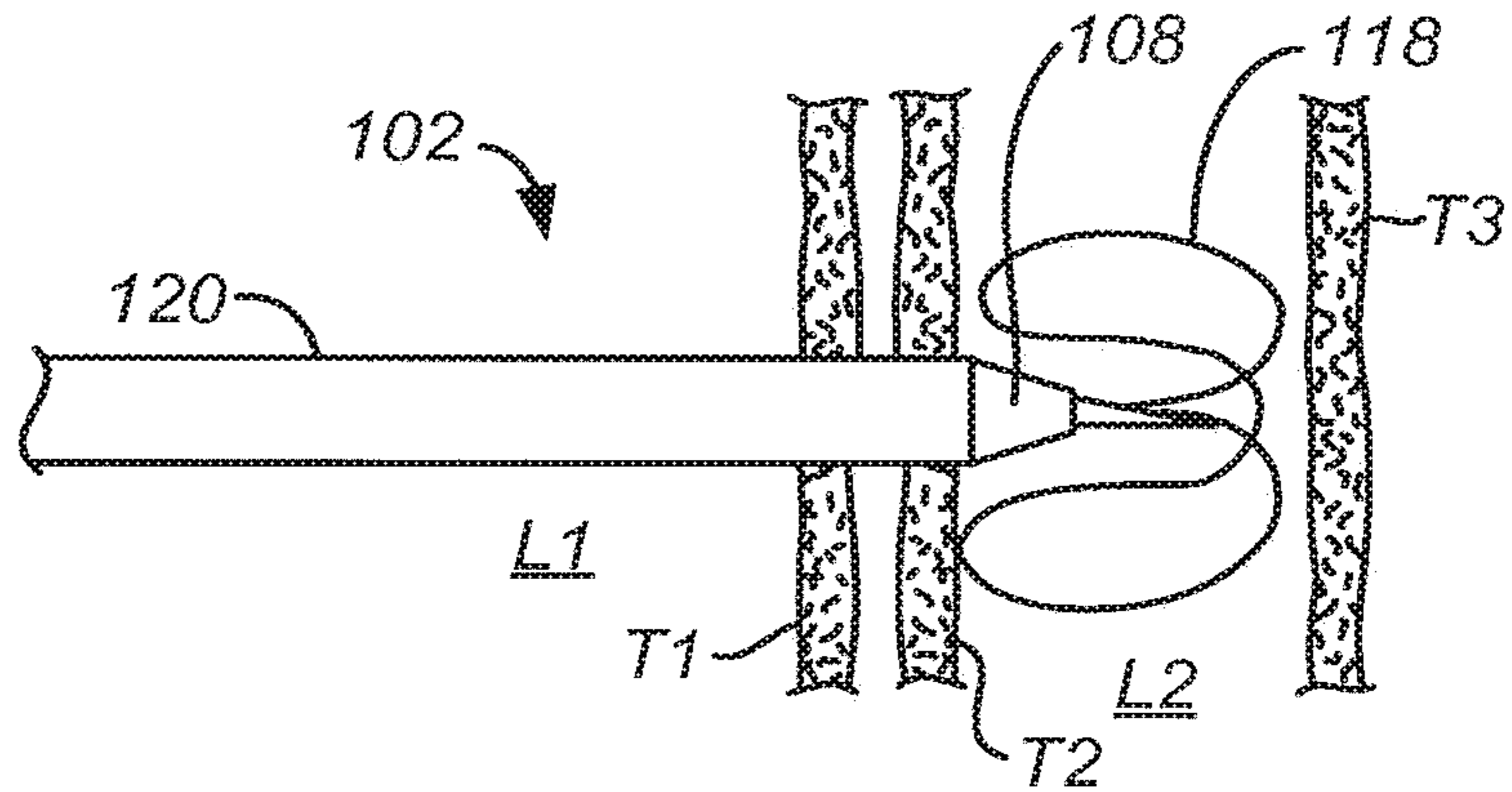


FIG. 6E

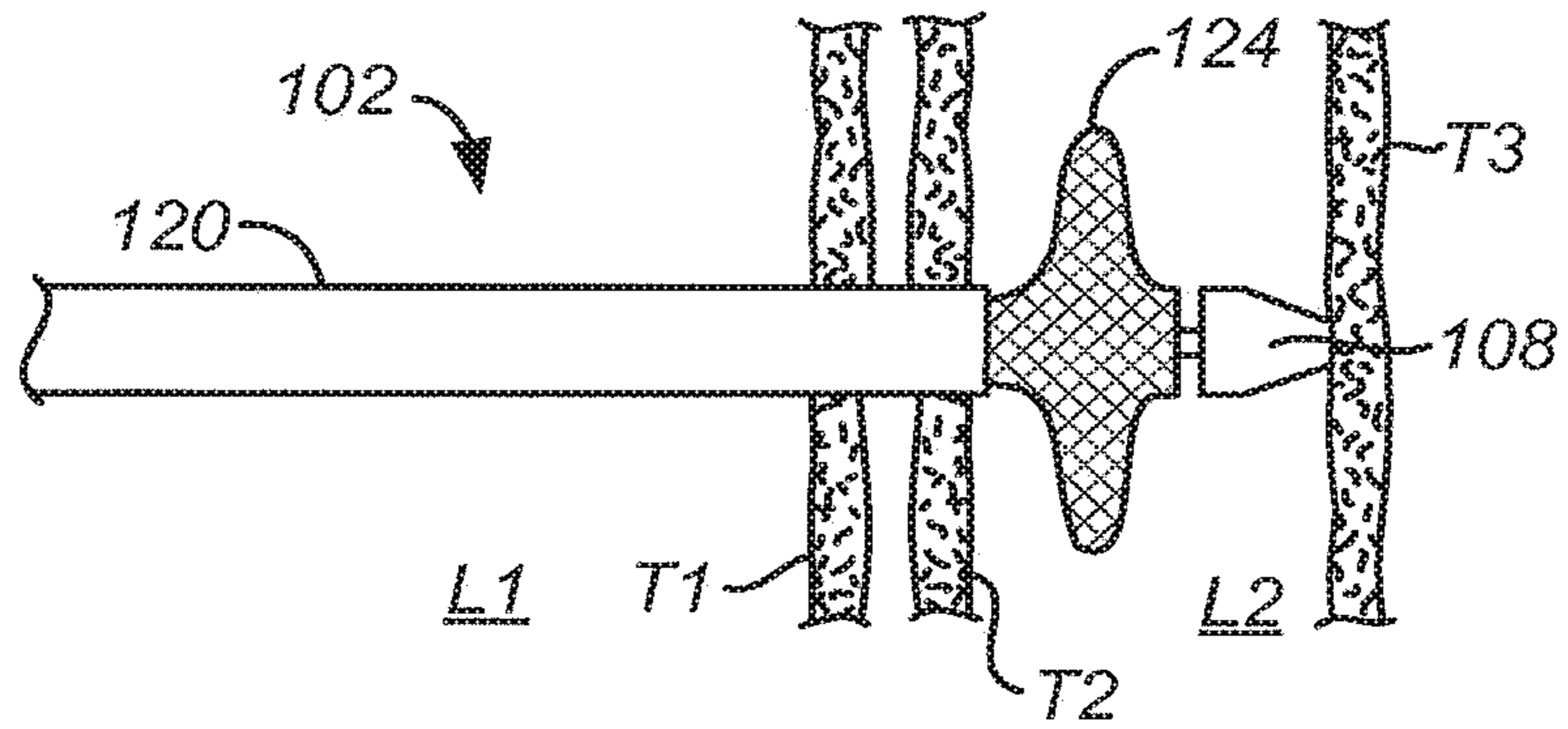


FIG. 6F

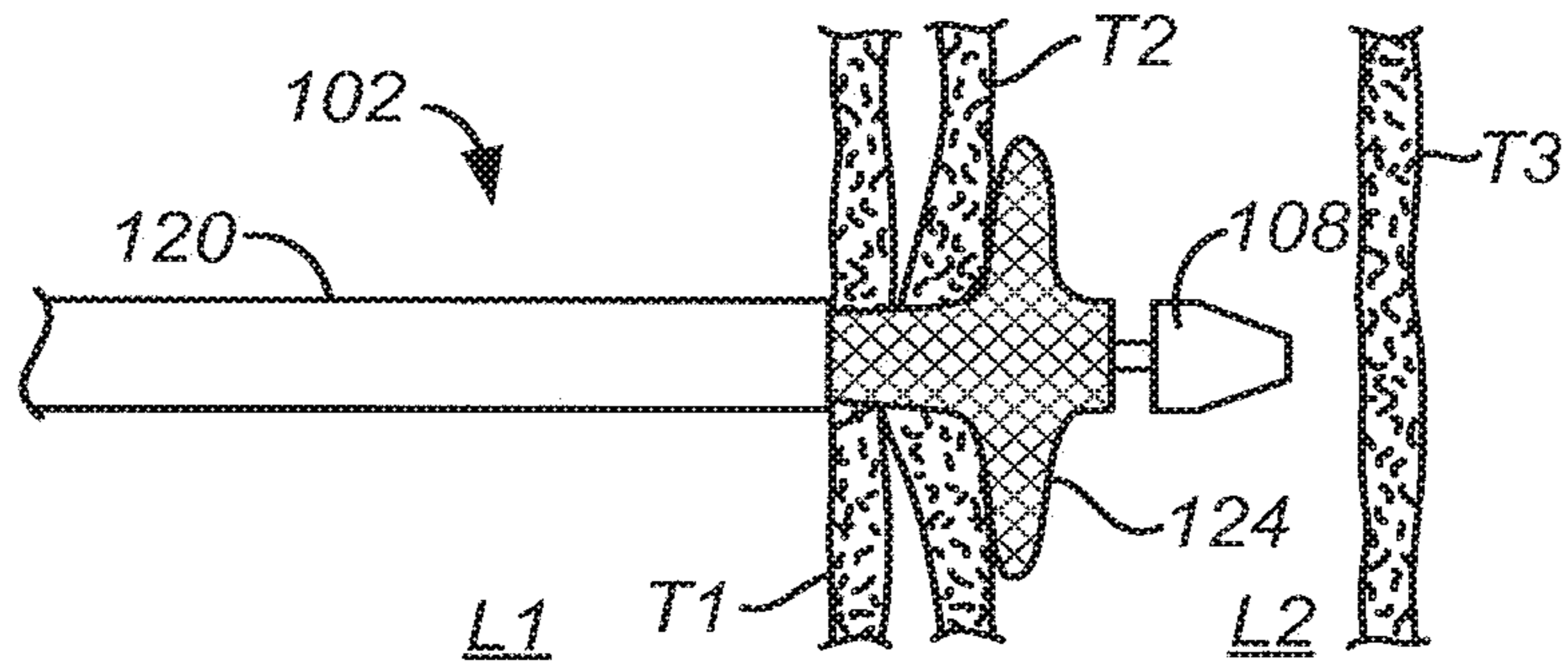
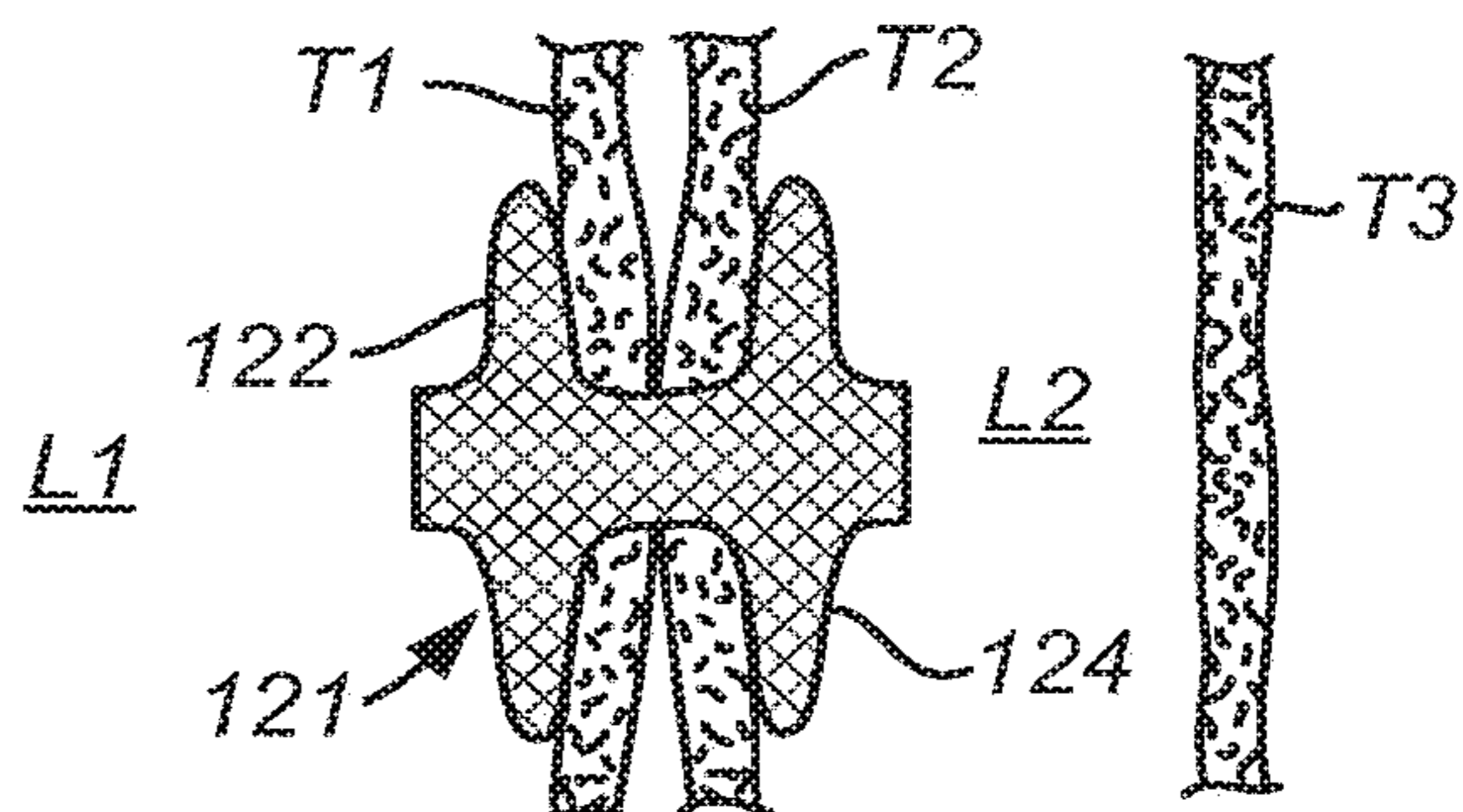


FIG. 6G



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**APPARATUS AND METHOD FOR
DEPLOYING STENT ACROSS ADJACENT
TISSUE LAYERS**

CROSS REFERENCE TO RELATED
APPLICATIONS

This application is a continuation of U.S. application Ser. No. 15/331,233, filed on Oct. 21, 2016, which is a continuation of U.S. application Ser. No. 13/364,265, filed on Feb. 1, 2012, and issued as U.S. Pat. No. 9,888,926, which is a continuation of U.S. application Ser. No. 12/772,762, filed on May 3, 2010, and issued as U.S. Pat. No. 8,357,193, which claims benefit of provisional application No. 61/182,312, filed on May 29, 2009, the full disclosures of which are incorporated herein by reference. The disclosure of the present application is related to those of commonly owned copending application Ser. No. 12/427,215, filed on Apr. 21, 2009; Ser. No. 12/757,408, filed on Apr. 9, 2010, and Ser. No. 12/757,421, filed on Apr. 9, 2010, the full disclosures of which are incorporated herein by reference.

FIELD

1. Field of the Invention

The present invention relates generally to medical devices and methods. More particularly, the present invention relates to inter-luminal stents and anchors as well as catheters and methods for their deployment.

A number of inter-luminal endoscopic procedures require precise placement of tissue anchors or stents. For example, a number of procedures may be performed by entering the gastrointestinal (GI) tract through a first organ or structure, such as the esophagus, stomach, duodenum, small intestine, or large intestine, and delivering the anchor or stent to adjacent organs and structures such as the bile duct, the pancreatic duct, the gallbladder, the pancreas, cysts, pseudocysts, abscesses, and the like.

Such endoscopic procedures often require the delivery of a tissue anchor or stent to secure adjacent tissues or organs and optionally to provide an opening therebetween. Inter-luminal tissue anchors, typically referred to as stents when they include a central lumen, are used to enable fluid communication between adjacent ducts, organs or lumens. Often, precise placement of the tissue anchor or stent is necessary, especially when the tissue anchor or stent has well defined anchoring elements at the proximal and/or distal ends, the device is used to secure adjacent lumens, or the device is placed within a duct at a precise location and secured at the proximal and/or distal ends.

When deploying a stent or other tissue anchor between adjacent body lumens, organs, or other structures, it is typically necessary to penetrate a wall of both the first body lumen through which access is established and a wall of a second body lumen which is the target of the procedure. When initially forming such access penetrations, there is significant risk of leakage from either the access body lumen or organ. In some cases, such as when accessing the bile duct, loss of the body fluid into surrounding tissues and body cavities can present substantial risk to the patient. Thus, it would be desirable to be able to establish the initial penetrations needed to deploy a stent or anchor while minimizing the risk of body fluid leakage. The risk of body fluid leakage can be exacerbated when multiple catheters or other tools are needed for placement of the stent or other anchor. In particular, the need to exchange tools over a guidewire or

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through an access catheter can both prolong the procedure and increase the risk of body fluid leakage during the procedure.

Thus, it would be desirable to minimize both the time and the number of tools which are needed when endoscopically placing stents or other anchors between adjacent body lumens or organs.

It would be further desirable to provide catheters and access tools which are capable of being deployed from endoscopes to access adjacent body lumens or cavities while minimizing the risk of leakage. It would be particularly desirable to provide catheters and tools which include all elements and capabilities needed to both penetrate the luminal walls and place the stent or other anchor between said walls, thus eliminating the need to exchange tools during an access procedure. It would be still further desirable if such tools and access methods could continually apply tension on the luminal walls to maintain said walls in close apposition during the stent or other anchor placement, thus further reducing the risk of body fluid loss during the procedure prior to final deployment of the stent or other tissue anchor. At least some of these objectives will be met by the inventions described below.

BACKGROUND

2. Description of the Background Art

US2009/0281379 and US2009/0281557 describe stents and other tissue anchors of the type that can be deployed by the apparatus and methods of the present invention. The full disclosures of these publications are incorporated herein by reference. US 2003/069533 describes an endoscopic transduodenal biliary drainage system which is introduced through a penetration, made by a trans-orally advanced catheter having a needle which is advanced from the duodenum into the gallbladder. U.S. Pat. No. 6,620,122 describes a system for placing a self-expanding stent from the stomach into a pseudocyst using a needle and an endoscope. US 2005/0228413, commonly assigned with the present application, describes a tissue-penetrating device for endoscopy or endosonography-guided (ultrasonic) procedures where an anchor may be placed to form an anastomosis between body lumens, including the intestine, stomach, and gallbladder. See also U.S. Pat. Nos. 5,458,131; 5,495,851; 5,944,738; 6,007,522; 6,231,587; 6,655,386; 7,273,451; 7,309,341; US 2004/0243122; US 2004/0249985; US 2007/0123917; WO 2006/062996; EP 1314404 Kahaleh et al. (2006) *Gastrointestinal Endoscopy* 64:52-59; and Kwan et al. (2007) *Gastrointestinal Endoscopy* 66:582-586. Shaped balloons having differently sized segments and segments with staged opening pressures are described in U.S. Pat. Nos. 6,835,189; 6,488,653; 6,290,485; 6,022,359; 5,843,116; 5,620,457; 4,990,139; and 3,970,090.

SUMMARY OF THE DISCLOSURE

The present invention provides methods and apparatus for establishing transluminal access between a first body lumen and a second body lumen. Such transluminal access may be intended for any medical purpose but will usually be intended for performing transluminal therapeutic endoscopy where the first body lumen is typically within the gastrointestinal (GI) tract, including the esophagus, the stomach, the duodenum, the small intestines, and the large intestines. The second body lumen, which is the target of the access, will

typically be an organ or other tissue structure which lies adjacent to the gastrointestinal tract (or may be another part of the GI tract), including the bile duct, the pancreatic duct, the gallbladder, cysts, pseudocysts, abscesses, the pancreas, the liver, the urinary bladder, the duodenum, jejunum, and colon. Particular procedures which may benefit from the access methods and apparatus of the present invention include gastrojejunostomy, gastroduodenostomy, and gastrocolostomy. Other procedures which can benefit from the methods and apparatus of the present invention include vascular bypass including porto systemic shunts and transjugular intrahepatic portasystemic shunt (TIPS) procedures.

The methods and systems of the present invention are advantageous in a number of ways. For example, by providing an ability to dock a stent or anchor deployment catheter with an endoscope introduced to the first body lumen, a very stable platform is provided for sequentially accessing tools to penetrate the luminal walls, maintain the luminal walls in apposition, and deploy the stent or other anchor while the luminal walls are maintained in apposition. By maintaining a substantially continuous apposition of the walls at all times after the initial penetration, the risk of body fluid leakage into body cavities surrounding the lumens is minimized. A further advantage provided by the methods and systems herein is the elimination of the need to deploy a guidewire. By deploying a penetrating needle from the stent/anchor placement catheter to form the initial penetration and subsequently introducing the stent delivery tool(s) over the needle using the same catheter, the duration of the procedure can be reduced and the need to exchange tools over the guidewire is eliminated. A still further advantage provided by the methods and apparatus of the present invention is the ability to deploy a tension wire from the needle which is initially used to penetrate the luminal walls. By deploying an anchor on the distal end of the tension wire on the luminal wall of the second body lumen, tension can be maintained to hold the luminal walls in apposition while the stent/anchor delivery tool is advanced over the needle.

The stents and anchors which are deployed by the methods and apparatus of the present invention will have distal and proximal flange elements which, at the end of the implantation procedure, will engage the luminal walls and hold the luminal walls together. In addition, the flanges and stent/anchor will seal sufficiently against the luminal walls to inhibit leakage from the time of their initial deployment. Usually, the stent/anchors will include or define a central opening or passage to allow the exchange of fluid between the first body lumen and the second body lumen, often being drainage of fluid from the second body lumen into the first body lumen, e.g., for gallbladder or bile duct drainage. A number of suitable stent/anchors are described in co-pending application US 2009/0281557, the full disclosure of which is incorporated herein by reference.

In a first aspect of the present invention a device is used to deliver a tissue stent or anchor in a controlled and predetermined manner. The controlled delivery device is introduced through the working channel of an endoscope and includes a proximal handle that provides control of delivery and a catheter that extends from a distal end of the proximal handle to the distal end of the device. The handle has a coupling member for removable attachment to the endoscope to provide a stable deployable platform. The catheter includes an outer sheath, at least one shaft (e.g., an inner catheter or pusher tube) that is used to deploy the tissue anchor, and a tapered distal tip. The handle has coaxial sliding elements that control at least three operations,

including device catheter positioning, distal anchor deployment, and proximal tissue anchor deployment. Such devices and apparatus will typically further include a first lock and a second lock for securing the first sliding element and the second sliding element, respectively. The ability to lock the sliding elements allows deployment of other components of the apparatus while maintaining the same relative position of the locked components.

The shaft and sheath of the catheter of the apparatus will be coaxially disposed so that the stent or anchor may be held over the shaft and constrained by the sheath. Thus, when using a self-expanding stent or anchor, the distal stent or anchor can be deployed by retracting the sheath over the stent or anchor while maintaining constraint of the proximal stent/anchor until deployment is desired. As described in more detail below, this allows the distal flange to be deployed and used to pull back on the wall of the second body lumen to maintain apposition as the proximal flange is deployed to complete the stent/anchor implantation.

Usually, the catheter shaft will have an axial passage extending therethrough. In some embodiments, the axial passage may be adapted to receive a guidewire. Usually, however, the catheter will further comprise a needle which is slidably disposed in the axial passage of the shaft. The needle will have a tissue penetrating tip, usually being sharpened, pointed or having an electrosurgical element, and will be operatively connected to a third slider or actuator on the handle, allowing a user to deploy the needle from the catheter, while the catheter is attached to the endoscope, in order to initially penetrate the luminal walls. Immediately after penetrating the luminal walls, the shaft and sheath of the catheter may be advanced over the needle to pass through the penetration in the luminal walls. Usually, the distal tip of the shaft will be tapered or have a cutting element to facilitate opening the passage through the luminal walls. The sheath may then be refracted over the shaft, again using the slider on the handle, in order to deploy the stent/anchor as discussed above.

In a still further specific aspect, the device may include a tension wire which is slidably disposed in an axial passage of the needle. The tension wire has an anchor at its distal end which can engage a wall of the second body lumen to provide tension as the catheter shaft and sheath are advanced over the needle. Typically, the anchor comprises a self-expanding structure formed integrally with the tension wire, usually comprising a plurality of loops which deploy rearwardly to form a concave structure or the wall of the second body lumen, e.g. where the concave structure provides clearance for advancing the catheter shaft and sheath past the luminal walls. A particular advantage of the concave structure is that it will protect against accidental needle penetrations after the anchor is deployed.

In a second aspect of the invention, methods for delivering a stent or other luminal anchor from a first body lumen to a second body lumen comprise advancing an endoscope having a working channel through the first body lumen to a target site on a wall of the first lumen. A stent deployment catheter is advanced through the working channel of the endoscope, and a handle control mechanism on the stent deployment catheter is attached to the endoscope so that the handle is immobilized relative to said endoscope. The stent deployment catheter assembly includes a shaft, a self-expanding stent (or anchor structure) carried on the shaft, and a sheath constraining the stent on the shaft, and the handle is used to sequentially manipulate the various catheter components in order to deploy the stent. Usually, the catheter assembly is advanced from the first body lumen,

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through the apposed walls at the target site and into the second body lumen through a passage in the luminal walls. After positioning the catheter, the sheath is retracted relative to the endoscope handle and shaft by a distance sufficient to release a distal portion of the stent to form a distal flange. The stent deployment assembly may then be pulled proximally, typically using controls on the handle, to engage the distal flange against the wall of the second body lumen to draw the two luminal walls into closer apposition. The sheath is then further retracted relative to the endoscope handle and shaft to release the remaining portion of the stent to deploy a proximal flange against the wall of the first body lumen.

In some embodiments, the passage through which the stent deployment catheter is advanced may be pre-formed with separate tool(s), for example using trocars or other instruments as described in co-pending application Ser. No. 12/757,408, the full disclosure of which is incorporated herein by reference. More usually, however, the passage through the luminal walls will be formed by advancing a needle carried by the stent deployment catheter relative to the handle and endoscope to penetrate the needle through the apposed luminal walls. When using the "on-board" needle, the stent deployment catheter may then be advanced over the needle and through the apposed walls after the needle has penetrated the apposed walls. Preferably, tension will be applied to the apposed walls while the stent deployment catheter is advanced, typically by positioning an anchor on a tension wire on the luminal wall of the second body lumen. In the exemplary embodiments, the tension wire is deployed through an axial passage in the needle. Applying tension reduces the chance of accidental leakage of body fluids during the stent deployment. Alternatively, tension could be applied using separately deployed T-tags or other tethers.

In this specific embodiment, the stent deployment catheter is advanced by manually advancing a catheter slider on the handle, where the catheter slider is coupled to the catheter assembly to move the shaft, sheath, and stent in unison relative to the handle and endoscope. Similarly, retracting the sheath will comprise manually retracting a second slider on the handle, typically a collar on the catheter slider, where the second slider is coupled to the sheath to move the sheath relative to the shaft, the stent, handle, and endoscope. Thirdly, advancing the needle will typically comprise manually advancing a needle slider on the handle, where the needle slider is coupled to said needle to move the needle (which optionally carries the tension wire) relative to the shaft, stent, handle, and endoscope. In contrast, the tension wire and anchor are typically deployed by direct manual movement of a proximal end of the wire which extends through the central passage of the needle and out of the proximal end of the handle.

In a third aspect of the present invention, a catheter for delivering a self-expanding stent through apposed luminal walls comprises a shaft, a needle, a tension wire, a self-expanding stent, and a retractable sheath. The shaft has a distal end, a proximal end, and an axial passage there-through. The needle is slidably positioned in the axial passage of the shaft and has a tissue-penetrating distal tip that can be advanced distally beyond the distal end of the shaft and retracted proximally within the passage of the shaft. The needle also has an axial passage therethrough, and the tension wire is slidably positioned in the axial passage of the needle. The tension wire includes a deployable anchor at its distal end where the anchor can be distally advanced beyond the distal tip of the needle and proximally retracted into the axial passage of the needle. The self-expanding stent

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is carried coaxially over the shaft and is constrained by the retractable sheath which is disposed thereover, as well as over the shaft. By proximally retracting the sheath, the stent can be released from constraint to deploy across the luminal walls.

The catheter typically further comprises a handle having a body with a coupling member that can be removably secured to a proximal end of an endoscope to position the catheter shaft within a working channel of the endoscope. The handle usually includes a catheter slide actuator to selectively advance and retract the catheter shaft within the working channel of the endoscope while the handle is secured to the endoscope. The handle usually also includes a second slide actuator, typically a collar on the catheter slide actuator, to selectively advance and retract the sheath over the shaft to release the self-expanding sheath from constraint. Additionally, a needle slide actuator is usually provided to selectively advance and retract the needle relative to the shaft.

The anchor on the tension wire may have a variety of configurations, but will usually be a self-expanding structure formed integrally with the tension wire. In this specific example, the self-expanding structure comprises a plurality of loops which deploy rearwardly to form a concave structure over the wall of the second body lumen, where the concave structure provides clearance for advancing the shaft and sheath through the luminal walls and protects the needle tip to inhibit accidental punctures.

The catheter may further comprise a port disposed on or otherwise coupled to a proximal end of the needle. The port may be used for aspiration and/or perfusion through the axial passage of the needle. For example, the port can allow for detection of when the needle has been advanced into the second body lumen as fluid from the second lumen may be aspirated through the port.

In the fourth aspect, the present invention provides methods for delivering a stent or other luminal anchor from the first body lumen, through apposed luminal walls, to a second body lumen. The method comprises positioning an endoscope in the first body lumen adjacent to a target site on a luminal wall. A catheter assembly is advanced through a working channel of the endoscope to locate a distal region of the catheter assembly at the target site. A needle carried by the catheter assembly may then be penetrated through the apposed walls at the target site, and an anchor on the distal end of a tension wire deployed in the second body lumen, typically from an axial passage within the needle. By drawing proximally on the tension wire (usually together with the needle), tension may be maintained on the walls to maintain the walls in close apposition to inhibit leakage of body fluids. A stent deployment sub-assembly which carries the stent is then advanced over the needle while maintaining tension on the tension wire. A distal flange on the stent may be expanded in the second body lumen, and the stent deployment sub-assembly drawn proximally to pull the distal flange against the wall of the second body lumen to maintain the walls in apposition, allowing the anchor on the tension wire to be withdrawn. While maintaining the walls in apposition with the distal flange, the proximal flange on the stent may be expanded in the lumen to complete the implantation. The catheter may then be withdrawn from the body lumens.

In particular instances, the anchor may be deployed by advancing the tension wire through an axial passage of the needle after the needle has penetrated through the apposed walls. The anchor will usually be self-expanding and be formed integrally with the tension wire. Thus, the self-

expanding anchor will deploy as the tension wire is advanced from the needle allowing the anchor to be released from the constraint of the axial passage of the needle. In specific examples, the self-expanding structure comprises a plurality of loops which deploy rearwardly to form a concave structure over the wall of the second body lumen, where the concave structure provides clearance for advancing the stent deployment sub-assembly across the walls.

In most embodiments, the stent will also be self-expanding and be deployed by retracting a sheath which is part of the stent deployment sub-assembly. Usually, the sheath will be sequentially retracted to first deploy the distal flange and, after drawing the distal flange against the wall of the second body lumen, the sheath may be further retracted to deploy the proximal flange and complete implantation of the stent across the luminal walls.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a first embodiment of a stent deployment apparatus constructed in accordance with the principles of the present invention.

FIG. 2 is a cross-sectional view of the distal end of the stent deployment apparatus of FIG. 1, taken along line 2-2 of FIG. 1.

FIGS. 3A-3E illustrate use of the stent deployment apparatus of FIG. 1 for deploying a stent through apposed luminal walls according to the principles of the methods of the present invention.

FIG. 4 illustrates a second embodiment of the stent deployment apparatus of the present invention.

FIGS. 5A-5E illustrate sequential actuation of the various tools of the stent deployment apparatus of FIG. 4.

FIGS. 6A-6G illustrate use of the apparatus of FIG. 4 for deploying a stent across apposed luminal walls in accordance with the principles of the methods of the present invention.

DETAILED DESCRIPTION

The device 10 of FIG. 1 includes a control handle 12 having a body 14 with a first slide actuator 15 with knob 16 and lock 20. A second slide actuator 18 with lock 22, scope locking mechanism 24, catheter body 26, a sheath 27, shaft 28, stent lock 30, distal tapered tip 32 and stent or other tissue anchor 34 (FIG. 2).

The distal end of endoscope or echo-endoscope 40 (FIG. 3A-3E) is positioned usually via trans-oral entry adjacent to a target location within the GI tract. A puncture is made at the desired location using a 19 gauge needle (typically an electrosurgical needle) followed by placement of a guidewire 102 through the needle lumen and optional balloon dilation over the guidewire or by using an expanding trocar as described in co-pending application Ser. No. 12/757,408 filed on Apr. 9, 2010, the full disclosure of which was previously incorporated herein by reference.

The catheter body 26 is then advanced over the guidewire 102 through the working channel of the endoscope 40 and is secured to the proximal end of a working channel using scope locking mechanism 24 to locate the catheter body 26 with a tip 32 approximately 1 cm outside of the distal end of the working channel, as in FIG. 3A.

The first slide actuator 15 is distally advanced using knob 16, after releasing lock 20, on handle 12, thus moving the assembly of catheter body 26, shaft 28, and stent 34, in the distal direction and through the tract formed through tissue T1 and tissue T2 and moving distal tapered tip 32 from

lumen L1 to lumen L2 as in FIG. 3B. Lock 20 is then reengaged, securing first slide actuator 15 to control handle body 14.

A distal flange segment 42 of the tissue anchor 34 is now expanded by moving the second slide actuator 18 in the proximal direction to retract sheath 27. The second slide actuator is pulled back to a predetermined position part way along the proximal extension 17 of the first slide actuator 15, after releasing second lock 22 as in FIG. 3C. A portion of lock 22 (FIG. 1) of second slide actuator 18 moves in a track (not shown), where said lock 22 engages a stop at a predetermined position, thereby stopping the proximal movement of actuator 18. Said predetermined position is calibrated to allow only the distal flange 42 of tissue anchor 34 to be released from constraint by sheath 27 and to expand. Said proximal motion of second slide actuator 18 retracts the sheath 27, while the shaft 28 is held in place, this releasing the distal portion of tissue anchor 34 from constraint.

The first slide actuator 15 is now moved slowly in the proximal direction using knob 16, after releasing lock 20, on handle 12, thus moving the expanded distal anchor flange 42 against the inner surface of tissue T2 of lumen L2, and positioning tissue T1 closer to tissue T2, holding lumen L1 and L2 in close apposition as in FIG. 3D. Stent lock 30 (FIG. 2) holds the proximal end of the tissue/stent anchor 34 firmly allowing proximal traction against tissue T2. Lock 20 is then reengaged, securing first slide actuator 15 to control handle body 14.

A proximal segment 44 of the tissue anchor stent 34 is now expanded by moving the second slide actuator 18 in the proximal direction to a position at or near the proximal end of the first slide actuator 15, after releasing lock 22 as in FIG. 3E to further retract the sheath 27. The proximal end of the tissue anchor stent 34 releases from stent lock 30 (FIG. 2) as the second slide actuator 18 reaches the proximal end of its travel. This releases the entire tissue anchor, which in this example has a central lumen 46 allowing fluid communication between lumens L1 and L2. The device 10 is now removed, leaving the tissue anchor 34 with central lumen 46 implanted between lumen L1 and lumen L2 with fluid communication being established.

Of particular interest in advanced therapeutic endoscopy is the drainage of bile from the gallbladder into the duodenum or stomach. This is accomplished endoscopically from within the GI lumen of the duodenum or stomach and requires that the gallbladder be located using transluminal imaging, such as endoscopic ultrasound (EUS), followed by penetration through the GI lumen and gallbladder wall and precise placement of a drainage stent between these structures. During the placement of the drainage stent, it is necessary that close apposition of the gallbladder and GI lumen be maintained to prevent bile leakage into the peritoneal cavity, a situation that can cause peritonitis which can be fatal. In this instance, delivery of a tissue anchor or luminal approximating stent requires precise control allowing that close apposition is maintained throughout the procedure and throughout the course of therapy. Using the devices of the present invention tissue stents and anchors, such as those described above or in co-pending application US 2009/0281557, can be precisely delivered.

An alternative embodiment of the stent deployment system of the present invention is illustrated in FIGS. 4 and 5A-5E. This alternative system is specifically designed for direct delivery and implantation of the stent or other anchor without use of a guidewire and allows the manipulation of all components of the system to form a single handle while the handle is secured to an endoscope used to access the first

body lumen to provide a stable implant delivery platform. The components of the system have been optimized to minimize the risk of body fluid leakage during the stent or anchor implantation procedure, particularly enhancing the seal maintained on the penetration through the wall of the second body lumen to reduce leakage from that lumen.

As shown in FIG. 4, the alternative stent delivery system **100** comprises a catheter **102** attached at its proximal end to a distal end of a handle assembly **104**. The catheter **102** includes a plurality of coaxially disposed components as best seen in FIGS. 5A-5E. A catheter shaft **106** extends the entire length of the catheter (a portion of the distal end is broken away to show internal components) and is attached at its distal end to a tapered tip **108** which includes a leading end **110** usually has includes a cutting edge or element to cut tissue as the tip is advanced therethrough. A needle **112** having a tissue-penetrating tip **114** is slidably received within an axial passage of the shaft **106** so that the needle can be extended distally beyond the distal end of the catheter, as shown in FIG. 5B, even when all other components are maintained within the catheter. A tension wire **116** is slidably disposed within an axial passage of the needle **112** and includes an anchor structure **118** which can be deployed when it is extended distally beyond the tip **114** of the needle **112**, as illustrated in FIG. 5C. The entire catheter **102** (distal to the handle **104**) is covered by a retractable sheath **120**, and the sheath maintains radial constraint on a self-expanding stent **122** or other anchor, allowing deployment of the stent by retraction of the sheath, as shown in FIG. 5E. The catheter **102** is shown in its initial delivery configuration in FIG. 5A where all system components are retracted within the sheath, with the needle **112** retracted within the shaft **106**, and the tension wire **116** retracted within the needle. In FIG. 5A, the needle **112** is shown distally extended beyond the distal end of the remaining components in the catheter **102**. In FIG. 5C, the anchor structure **118** of the tension wire **116** is shown distally extended beyond the distal tip **114** of the needle. In FIG. 5D, the sheath **120** is shown retracted relative to the shaft so that at least the cutting edge **110** of the tapered tip **108** is exposed beyond the distal end of the sheath **120**. Finally, in FIG. 5E, the catheter **102** is shown with all components fully extended (except for the sheath **120** which is retracted) and with the stent **122** shown in its radially expanded configuration having a proximal flange **124** and a distal flange **122**.

The handle assembly **104** comprises a plurality of slide actuators which permit selective advancement and retraction of the various components of the catheter **102**, as will now be described. The handle assembly **104** includes a body **130** having a coupling member **132** at its distal end. The coupling member **132** is selectively attachable to the proximal hub of an endoscope E (as shown in FIG. 6A) after the catheter **102** has been introduced through the working channel. From that point on in any procedure, the body **130** of the handle assembly **104** will remain fixed relative to the endoscope while the remaining components in the handle may be selectively advanced and retracted in order to deploy the various components of the catheter. In particular, a first tubular slider **134** is coupled to advance the needle and tension wire when it is pushed forward relative to the body **130**. A second tubular slider **136** is coupled to the catheter shaft and sheath in order to advance the shaft and sheath in unison when the slider **136** is pushed forward relative to the body **130**. The first and second tubular sliders **134** and **136**, however, are decoupled so that manipulation of the first tubular slider does not affect the position of the shaft and

sheath while manipulation of the second tubular slider **136** does not affect the position of the needle and tension wire.

The sheath may be retracted relative to the shaft and other system components using a collar **138** which is slidably disposed over the second tubular slider **136**. Refraction of the collar **138** retracts the sheath but leaves all other system components stationary relative to the body **130** and endoscope to which it is attached. A proximal handle **140** at the proximal end of the tension wire **116** extends out from a Touhy Borst fitting **142** when a Y-connector **144** attached to the proximal end of the needle **112**. The Y-connector **144** also includes an aspiration/infusion port **146** which is fluidly coupled to the central passage of the needle. The tension wire **140** may be advanced and retracted relative to all other system components by loosening the Touhy Borst fitting and manually advancing or retracting the handle **140**.

By manually advancing the tension wire **116** using the handle **140**, the anchor structure **118** is deployed. Usually, the anchor structure **118** is pre-shaped to assume a desired configuration when it is released from the confinement of the needle lumen. Conveniently, the anchor structure and the entire tension wire may be formed from Nitinol or other shape-memory alloy. In the exemplary elements, the anchor structure **118** comprises a plurality of loops which deploy rearwardly to form a concave structure (with the concave surface in the rearward or proximal direction), as illustrated in FIGS. 5C-5E. The structure may be formed from a single length of the wire which folds back on itself to form the illustrated structure. Alternatively, the wire could be split to form the multi-loop structure from a single larger loop. A variety of other geometries and structures could be provided for the anchor structure, including cones, conical spirals, multiple everting elements, and the like.

A detailed construction for the catheter handle showing the connections between the handle components and the catheter components is provided in Appendix A attached to this application.

Referring now to FIGS. 6A-6G, the stent deployment system **100** is illustrated in use for implanting stent **122** between tissue layers T1 and T2 and body lumens L1 and L2. Body lumen L2 has a back wall T3 which is to be protected during the procedure. As shown in FIG. 6A, an endoscope E is positioned within the body lumen L1, and the distal end of the catheter **102** is advanced through a working channel of the endoscope to be positioned adjacent to a target location TL on the luminal wall T1 of body lumen L1. Usually, visualization using the endoscope will be sufficient to properly locate the target location, but use of fluoroscopy, endoscopic ultrasound, or other imaging modes would also be possible.

After the target location TL has been identified, the needle **112** will be advanced through the target location on T1 and through a corresponding location on T2, as shown in FIG. 6B. The endoscope is not shown in FIGS. 6B-6G, but it would still be present as the catheter handle assembly **104** would have been connected to a proximal hub on the endoscope prior to needle advancement. The needle will be advanced by distally advancing the first tubular slider **134**. Successful entry into the lumen L2 can be confirmed by aspirating fluid through the needle lumen and port **146** on the Y-connector **144**. Usually, a lock or a limiter (not shown) will be provided on the handle assembly **104** so that forward advancement of the first tubular slider **134** is stopped at a depth which prevents penetration through the back wall T3 of the lumen L2.

Once the needle **112** has successfully reached the interior of body lumen L2, the anchor structure **118** will be deployed,

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as shown in FIG. 6C. Deployment is conveniently achieved by advancing handle 140 at the proximal end of the tension wire 116 to deploy the multi-lobed structure as described previously.

Once the anchor structure 118 has been successfully 5 deployed, the needle 112 and tension wire 116 may be retracted relative to the remaining components of the catheter and the endoscope in order to draw the anchor 118 proximally to close the tissue walls T1 and T2 closer together, as also shown in FIG. 6C.

After the tissue walls T1 and T2 are drawn into closer apposition, the tapered tip 114 of the catheter 102 may be exposed by partially retracting the sheath 120, as shown in FIG. 6D, and the catheter advanced through the needle penetration with the tapered tip (usually including a cutting 15 element) facilitating advancement and enlarging the penetration. Continued tension on the needle 112 and tension wire 116 help maintain apposition between tissue layers T1 and T2 during advancement of the catheter to reduce the risk of body fluid leakage from either body lumen, particularly 20 from the target lumen L2.

Once the catheter 102 has successfully entered second body lumen L2, as shown in FIG. 6E, the proximal flange 124 of the stent 122 may be deployed by further retracting the sheath 120 and the needle 112 and anchor structure 118 25 can be withdrawn. The proximal flange may then be drawn proximally against the wall of T2, as shown in FIG. 6F to reestablish apposition of the luminal walls during the remainder of the deployment procedure. The flange 124 may be retracted using the second tubular slider 136 which is 30 coupled to the shaft which carries the stent. A stent lock (not shown) or other structure is provided to prevent the stent from sliding over the shaft during the deployment procedure prior to full expansion of the stent. After the tension has been applied using the distal flange 124, the sheath 120 may be 35 further retracted, using sheath collar 138, to fully deploy the stent so that the proximal flange 122 engages a luminal surface of the first tissue layer T1, as shown in FIG. 6G. After the stent is deployed, the catheter including all components may be removed by detaching the handle from the 40 endoscope and withdrawing the entire structure. A central passage or opening through the stent provides for a fluid communication between lumens L1 and L2, typically for drainage of fluids from second body lumen L2 into the first body lumen L1.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims 50

What is claimed is:

1. A device, comprising:

- a shaft configured to support a self-expanding drainage device, the shaft comprising a distal end;
- a tissue penetrating member coaxial with the shaft, the 55 tissue penetrating member comprising an electro-surgical tip having a distalmost end that is coplanar with the shaft distal end;
- a holding component coaxial with the shaft, the holding component configured to deploy the self-expanding 60 drainage device from the shaft, wherein the holding component comprises a retractable sheath slidably disposed over the shaft; and
- a securing mechanism configured to maintain a plurality of predetermined positions of the holding component 65 relative to the shaft, the securing mechanism comprising:

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a first lock configured to maintain at least a first one of the plurality of predetermined positions between the holding component and the shaft and to prevent movement of the retractable sheath proximally with respect to the shaft, and

a second lock configured to maintain at least a second one of the plurality of predetermined positions between the holding component and the shaft and to prevent movement of the retractable sheath proximally with respect to the shaft;

wherein a guidewire is receivable within a lumen of the tissue penetrating member and a lumen of the shaft.

2. The device of claim 1, wherein the shaft comprises the self-expanding drainage device and the holding component with the self-expanding drainage device undeployed is movable to a first position relative to the shaft in which the self-expanding drainage device is partially deployed, and to a second position relative to the shaft in which the self-expanding drainage device is fully deployed from the shaft.

3. The device of claim 2, wherein the first position and second position are predetermined, and wherein one or both of the first position and the second position relative to the shaft is marked by visual or tactile indicia.

4. The device of claim 1, wherein the lumen of the tissue penetrating member and the lumen of the shaft form a contiguous lumen.

5. The device of claim 1, wherein the electro-surgical tip is configured to penetrate a second body site from a location within a first body site.

6. The device of claim 5, further comprising the self-expanding drainage device, wherein the self-expanding drainage device forms a distal flange and a proximal flange with a conduit therebetween when fully deployed from the shaft, and wherein the distal flange is configured to be 35 deployed within the second body site, and the proximal flange is configured to be deployed within the first body site.

7. A medical device, comprising:

- a shaft, wherein a distal end of the shaft includes an electro-surgical component that is coaxial with the shaft configured to create or enlarge an opening between first and second body sites, wherein the electro-surgical component comprises a distalmost tip that is coplanar with the shaft distal end;

- a self-expanding stent carried on the shaft proximal to and coaxial with the electro-surgical component;

- a sheath coaxial with the shaft, movably disposed over the shaft, and constraining the self-expanding stent on the shaft; and

- a securing mechanism comprising a first lock and a second lock,

- wherein the first lock is configured to maintain the sheath relative to the shaft such that the self-expanding stent is constrained;

- wherein, responsive to unlocking the first lock, the sheath is movable a first predetermined distance proximal relative to the shaft such that a portion of the self-expanding stent becomes unconstrained to deploy a distal flange of the self-expanding stent;

- wherein the second lock is configured to maintain the position of the sheath relative to the shaft at the first predetermined distance; and

- wherein, responsive to unlocking the second lock, the sheath is movable to a second predetermined distance proximal relative to the shaft such that a remaining portion of the self-expanding stent becomes unconstrained to deploy a proximal flange of the self-expanding stent.

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8. The medical device of claim 7, wherein the first and second distances are predetermined.

9. The medical device of claim 7, wherein the distal flange is configured to be deployed within the second body site, and the proximal flange is deployed within the first body site.

10. The medical device of claim 7, wherein the electro-surgical component includes a lumen configured to receive a guidewire therethrough.

11. The medical device of claim 7, wherein the electro-surgical component includes a tapered tip.

12. A device, comprising:

a shaft having a distal end, a proximal end and a lumen extending therebetween;

an electro-surgical component coaxially disposed on the distal end of the shaft and configured to create or enlarge an opening between adjacent tissues of a first body lumen and a second body, wherein the electro-surgical component comprises a distalmost tip that is coplanar with the shaft distal end;

a retractable sheath slidably and coaxially disposed over the shaft;

a securing mechanism comprising a first lock and a second lock; and

a self-expanding drainage device constrained between the shaft and the retractable sheath;

wherein the retractable sheath is configured to be proximally retracted to a first predetermined position relative

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to the shaft to deploy a distal flange of the self-expanding drainage device responsive to the first lock being unlocked;

wherein the first lock is configured to maintain the position of the sheath relative to the shaft at the first predetermined position;

wherein the retractable sheath is configured to be proximally retracted to a second position relative to the shaft to deploy a proximal flange of the self-expanding drainage device responsive to the second lock being unlocked; and

wherein the second lock is configured to maintain the position of the sheath relative to the shaft at the second position.

13. The device of claim 12, wherein a distance of the first position and a distance of the second position relative to the distal end of the shaft are predetermined.

14. The device of claim 12, wherein the distal flange is configured to be deployed within the second body, and the proximal flange is deployed within the first body lumen.

15. The device of claim 12, wherein the lumen of the shaft is configured to receive a guidewire therethrough.

16. The device of claim 12, wherein the electro-surgical component includes a tapered tip.

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